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APPLICATION NO.	F	LING DATE	FIRST NAMED INVENTOR	ATTORNEY I	OCKET NO.	CONFIRMATION NO.
09/393,803	i	09/10/1999	MARGARET A. LIU	19188	BPCA	3309
210	7590	11/30/2004		EXAMINER		
MERCK A	NC	LEFFERS JR, GERALD G				
P O BOX 20 RAHWAY,		50907		· ART U	JNIT	PAPER NUMBER
				163	1636	
			DATE MAILED: 11/30/2004			

Please find below and/or attached an Office communication concerning this application or proceeding.

	Application No.	Applicant(s)					
	09/393,803	LIU ET AL.					
Office Action Summary	Examiner	Art Unit					
	Gerald G Leffers Jr., PhD	1636					
The MAILING DATE of this communication appears on the cover sheet with the correspondence address							
Period for Reply	ALC CET TO EVOIDE AMONTH	(O) FDOM					
A SHORTENED STATUTORY PERIOD FOR REPLY THE MAILING DATE OF THIS COMMUNICATION.  - Extensions of time may be available under the provisions of 37 CFR 1.13 after SIX (6) MONTHS from the mailing date of this communication.  - If the period for reply specified above is less than thirty (30) days, a reply If NO period for reply is specified above, the maximum statutory period was reply received by the Office later than three months after the mailing earned patent term adjustment. See 37 CFR 1.704(b).	36(a). In no event, however, may a reply be ti within the statutory minimum of thirty (30) da will apply and will expire SIX (6) MONTHS fron cause the application to become ABANDONI	mely filed ys will be considered timely. n the mailing date of this communication. ED (35 U.S.C. § 133).					
Status							
1) Responsive to communication(s) filed on 03 Section 2015	eptember 2004.						
2a)⊠ This action is <b>FINAL</b> . 2b)□ This action is non-final.							
3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is							
closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213.							
Disposition of Claims							
4) ☐ Claim(s) 50-68 and 70-77 is/are pending in the 4a) Of the above claim(s) is/are withdraw 5) ☐ Claim(s) 64-68,70-73 and 75-77 is/are allowed 6) ☐ Claim(s) 50-63 and 74 is/are rejected.  7) ☐ Claim(s) is/are objected to.  8) ☐ Claim(s) are subject to restriction and/or Application Papers	vn from consideration.						
	_						
9) The specification is objected to by the Examiner. 10) The drawing(s) filed on is/are: a) accepted or b) objected to by the Examiner.							
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).							
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).							
11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.							
Priority under 35 U.S.C. § 119							
12) Acknowledgment is made of a claim for foreign a) All b) Some * c) None of:  1. Certified copies of the priority documents 2. Certified copies of the priority documents 3. Copies of the certified copies of the priority application from the International Bureau * See the attached detailed Office action for a list	s have been received. s have been received in Applica rity documents have been receiv u (PCT Rule 17.2(a)).	tion No red in this National Stage					
Attachment(s)							
Notice of References Cited (PTO-892)     Notice of Draftsperson's Patent Drawing Review (PTO-948)	4) 🔲 Interview Summar Paper No(s)/Mail D						
Notice of Draftsperson's Patent Drawing Review (PTO-948)     Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)     Paper No(s)/Mail Date		Patent Application (PTO-152)					

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#### **DETAILED ACTION**

Receipt is acknowledged of an amendment, filed 9/3/2004, in which claims 50-68 and 70-77 were amended. Claims 50-68, 70-77 are pending in the instant application.

Any rejection of record not addressed herein is withdrawn. This action is FINAL.

### **Priority**

Applicants' amendment of the first sentence of the specification in the papers filed 12 April 2002 is acknowledged. A corrected bibliography data sheet has been entered into the file along with this action.

## Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 50-63 & 74 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter that was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new rejection necessitated by applicants' amendment of the claims in the papers filed 9/3/2004.

Each of the new claims recites a limitation that specifies that the plasmid vector of the invention induces the co-expression in a eukaryotic host cell of at least two *and not more than* 

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three gene products (examiner's emphasis added). There is no literal or inherent support in the originally filed specification for this newly added limitation in the rejected claims. Therefore, the newly added limitation is impermissible NEW MATTER.

#### Conclusion

Claims 50-68, 70-77 are pending in the instant application, with claims 50-63 & 74 rejected herein. Claims 64-68, 70-73 and 75-77 are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gerald G Leffers Jr., PhD whose telephone number is (571) 272-0772. The examiner can normally be reached on 9:30am-6:00pm.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel can be reached on (571) 272-0781. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Gerald G Leffers Jr., PhD Primary Examiner Art Unit 1636

PRIMARY EXAMINER